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NEEDLE & ROSENBERG P C
127 PEACHTREE STREET N E
ATLANTA, GA 30303-1811

EXAMINER

WILSON, MICHAEL C

ART UNIT PAPER NUMBER

1632

DATE MAILED: 10/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,575

Applicant(s)

Cantrell et al.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above, claim(s) 1-58 and 81-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group II, claims 59-80 in the response filed 8-2-02, Paper No. 7, is acknowledged. The traversal is on the ground(s) that the examiner has not shown that a serious burden would result if Groups I, II and III were examined together. This is not found persuasive because the examiner set forth numerous reasons why the inventions were patentably distinct, why the inventions were not searched together and why each invention required different considerations in the restriction requirement. The inventions are of a different scope and the references which would be applied to one group of claims would not necessarily anticipate or render obvious the other group. For example, Etches (1997) of record taught that a hen egg fertilized either naturally or by artificial insemination has an embryos containing approximately 30,000 cells when expelled from the shell gland and it contains less cells while in the native reproductive system during deposition of calcium carbonate crystals or while in the surrogate shell (pg 435; Fig. 4 or 7). As to the question of burden of search, the literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Further, it is doubted that applicants would readily accept the rejection of the method of the elected invention over a reference which is related only to amount of embryo cells in the egg having a shell. Clearly different searches and issues are involved with each group.

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Therefore, the burden required to search and examine Groups I, II and III together would be undue.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-58 and 81-87 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Claims 59-80 are under consideration in the instant office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 59-80 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 59-64 are directed toward an oviposited avian or chicken egg comprising a native embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick.

Claims 65 is directed toward an oviposited chicken egg comprising a native embryo. Claim 77 is directed toward an egg produced by the method of claim 9, wherein the egg comprises and embryo. Claim 78 is directed toward an oviposited chicken egg comprising a native yolk and an embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick.

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Claim 79 is directed toward an oviposited chicken egg comprising a native yolk and an embryo having fewer than 20,000 cells, wherein the embryo can develop into a live chick. Claim 80 is directed toward an oviposited chicken egg comprising a native yolk and an embryo having fewer than 10,000 cells, wherein the embryo can develop into a live chick.

Oviposited eggs as in claims 59-65 and 77-80 are non-statutory subject matter because they are products of nature. Robertson (1997, J. Reprod. Fertility, Vol. 110, pg 205-211) taught oviposition encompasses depositing an egg into the infundibulum (pg 206, col. 1, 2nd para.; “Newly ovulated ova were obtained from the body cavity or the first few centimeters of the infundibulum of hens killed... ..approximately 15 minutes after oviposition.”). An oviposited egg encompasses an egg in the infundibulum. An oviposited, fertilized egg in the infundibulum has the number of cells required in the claims and is a product of nature. Therefore, the oviposited eggs are non-statutory subject matter because they are a product of nature.

The examples in the specification teach fertilizing chicken eggs after they have been laid by inserting sperm into the egg to make chicks (pg 36-37). However, the eggs outside of the body having the number of cells as required in the claims do not meet the requirements for having a specific or substantial utility. Etches (1997, Methods Mol. Biol., Vol. 62, pg 433-450) taught that a hen egg fertilized either naturally or by artificial insemination has an embryo containing approximately 30,000 cells when expelled from the shell gland and it contains less cells while in the native reproductive system during deposition of calcium carbonate crystals or while in the surrogate shell (see page 435 or Fig. 4 or Fig. 7). Using an egg outside of the body

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having less than 30,000 cells as claimed to make chicks is not a utility that is specific because eggs in the infundibulum having less than 30,000 cells have the same function, i.e. making avians. Using eggs to make avians is a general utility that is applicable to any avian egg having less than 10,000-30,000 cells, no matter where it is located. An egg outside of the body does not have a specific utility as compared to an egg having the same function located inside the body. For example, a machine-incubated egg does not have a utility that is specific as compared to a hen-incubated egg.

Claims 66-74 are directed toward an oviposited avian or chicken egg comprising a native embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick, and wherein the egg shell has an opening less than 4 cm. Claims 75 and 76 are directed toward an oviposited chicken egg comprising a zygote, wherein the zygote can develop into a live chick, and wherein the egg shell has an opening of less than 4 cm. Claims 66-74 lack utility for reasons cited above and because an egg having a window does not have a specific utility. The window does not confer any function to the egg that is different than an egg without a window. The window does not alter the avian produced from the egg. Therefore, an egg having a window as claimed does not have a utility that is specific as compared to an egg that does not have a window.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 59-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The summary of the claims can be found in the utility rejection above.

The examples in the specification teach fertilizing chicken eggs after they have been laid by inserting sperm into the egg to make chicks (pg 36-37). Therefore, the purpose of the eggs claimed is to make avians. The enablement rejection set forth below is based on how to use the eggs claimed to make avians - the sole disclosed purpose for the eggs claimed.

The prior art did not teach successful fertilizing avian eggs outside of the body or obtaining an embryo in a such manner such that an avian was produced. Therefore, it was unpredictable how to obtain such eggs. Etches (1997, Methods Mol. Biol., Vol. 62, pg 433-450) taught that a hen egg fertilized either naturally or by artificial insemination has an embryos containing approximately 30,000 cells when expelled from the shell gland and it contains less cells while in the native reproductive system during deposition of calcium carbonate crystals or while in the surrogate shell (see page 435 or Fig. 4 or Fig. 7). Therefore, using an oviposited egg

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having less than 30,000 cells as claimed to make chicks is not an enabled use that is specific to such an egg because non-oviposited egg having less than 30,000 cells have the same structure and function and are used to make chicks. Using the eggs claimed to make avians is a general use that is applicable to any avian egg having less than 30,000 cells, no matter where it is located. The location of the egg (i.e. oviposited) does not render the egg claimed as having a specific utility as compared to other eggs having the same function. For example, a machine-incubated egg does not have a utility that is specific as compared to a hen-incubated egg. Therefore, the specification does not provide an enabled use for the eggs claimed fertilized outside of the body that is specific to such eggs.

In addition, the specification does not provide an enabled use for oviposited eggs having an opening less than X cm/mm that is specific to such eggs. Eggs having an opening have the same function as those not having an opening - to make chicks - which is general and applicable to any avian egg no matter what size opening it has. The opening in the egg does not render the egg claimed as having a different function as compared to other eggs. For example, an egg having a blue dot does not function any differently than an egg without a blue dot. In addition, such an egg may not function to produce as chick because the claim does not require the opening is sealed. Therefore, eggs having an opening as claimed do not have an enabled use in the disclosure that is specific to such eggs.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 59-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "oviposited" in the claims is used to mean eggs "extruded from the vagina" (pg 5, line 25; pg 7, line 25), while the art at the time of filing used the term to describe an egg deposited into the infundibulum (Robertson, 1997, J. Reprod. Fertility, Vol. 110, pg 205-211; pg 206, col. 1, 2nd para.; "Newly ovulated ova were obtained from the body cavity or the first few centimeters of the infundibulum of hens killed... ..approximately 15 minutes after oviposition."). "Oviposited" eggs cannot be limited to eggs extruded from the vagina as defined in the specification.

The term "native" is indefinite because it is a relative term, is not adequately defined in the specification and the claim does not state to what the embryo or yolk is native. The specification defines native as "growing, living or produced in its place of origin." Thus, a native embryo is an embryo that develops and hatches in the same shell in which the female pronucleus was formed" However, such a conclusion cannot be made based on the definition provided. Any embryo living in a shell is an embryo "growing, living or produced in its place of origin" because

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it is in living a shell - its place of origin. The specification does not limit a "native embryo" to an embryo "that develops and hatches in the same shell in which the female pronucleus was formed"; it is merely an example. Furthermore, the definition does not limit a "native" embryo or yolk to an embryo or yolk growing, living or produced in its shell of origin. As such, the metes and bounds of "native" using the information in the specification are confusing and are not clearly set forth in the specification.

The phrase "the egg shell" in claims 66, 73-76 lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 59-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449).

Tanaka taught a laid egg comprising a freshly fertilized ovum (pg 447, col. 2, "Materials and Methods;" pg 448, Fig. 1) made transferring a day old fertilized ovum into the birth canal of the chicken. A shell formed around the ovum as it passed through the recipient hen's reproductive system, the egg was laid on the day following the transfer (pg 448, col. 1, line 4)

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and a chick hatched (pg 448, col. 2, first full para., line 9). The day old fertilized ovum had less than 10,000 cells as claimed because a zygote is one cell.

“Native” is defined as growing, living or produced in its place of origin. The specification concludes, “Thus, a native embryo is an embryo that develops and hatches in the same shell in which the female pronucleus was formed. Thus, the embryo is descended from the native ovum” (pg 11, line 27 to pg 12, line 3). The embryo in the egg taught by Tanaka is a “native embryo” because it is growing in its place of origin - a shell - and because it is descended from the native ovum. The definition of a “native embryo” is not limited to an embryo that develops and hatches in the same shell in which the female pronucleus was formed. Therefore, claims 64, 65 and 78-80 have been included. Claims 66-76 are included because “the egg shell” lacks antecedent basis (see 112/2nd). Claim 77 is included because the egg produced by the method of claim 9 has the same structure and function as the egg taught by Tanaka.

5. Claims 59-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnston (1998, Poultry Science, Vol. 77, pg 142).

Johnston taught a fertilized oocyte (6 lines from the bottom) which is equivalent to the eggs claimed. The egg used for fertilization is oviposited (line 9). A fertilized oocyte is equivalent to an embryo or zygote, and is less than 10,000 cells as claimed because it is one cell that proliferates (last sentence). The fertilized oocyte is a “native” embryo or zygote because it is growing and living “in its place of origin” as defined in the specification (pg 11, line 27). While an example of a “native embryo” is an embryo that develops and hatches in the same shell in

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which the female pronucleus was formed (sentence bridging pg 11-12), embryos/zygotes do not have to be maintained in a shell, the definition of “native” embryos/zygotes is not limited to embryos/zygotes in shells, or in the same shell in which the female pronucleus was formed.

Claims 66-76 are included because “the egg shell” lacks antecedent basis (see 112/2nd).

Claim 77 is included because the egg produced by the method of claim 9 has the same structure and function as the egg taught by Johnston.

6. Claims 59-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Perry (1988, Nature, Vol. 331, pg 70-72).

Perry taught a fertilized oocyte recovered from the oviduct of a hen surrounded by a capsule of dense, viscous albumen (pg 71, Fig. 1A caption). The egg is “oviposited” because it is present in the infundibulum and also because it is removed from the body. The fertilized oocyte is “native” because it is maintained in its capsule of albumen (Fig. 1B). The embryo taught by Perry is a “native embryo” because it is descended from the native ovum (pg 12, line 1). The definition of “native” embryos/zygotes is not limited to embryos/zygotes in the same shell in which the female pronucleus was formed (sentence bridging pg 11-12). Perry also taught the embryos develop into live chicks (pg 72, Table 1, last column, third row). Claims 66-76 are included because “the egg shell” lacks antecedent basis (see 112/2nd). Claim 77 is included because the egg produced by the method of claim 9 has the same structure and function as the egg taught by Perry. Thus, Perry anticipates the claims.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 59-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449), Johnston (1998, Poultry Science, Vol. 77, pg 142), or Perry (1988, Nature, Vol. 331, pg 70-72) in view of Goldberg (1992, Ped. Research, Vol. 32, pg 23-26).

Tanaka, Johnston and Perry taught an oviposited avian egg having less than 10,000 cells as claimed (see 102 rejections above). Tanaka, Johnston and Perry did not teach making a window less than 5 mm as claimed.

However, Goldberg taught making a 1 mm window in avian eggs having embryos to inject various solutions (para. bridging pg 23-24).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain an oviposited avian egg having less than 10,000 cells as taught by Tanaka, Johnston or Perry and make a 1 mm window in the egg as taught by Goldberg. One of ordinary skill in the art at the time of the invention would have been motivated to inject various solutions into the eggs of Tanaka, Johnston or Perry to study the effects of teratogenic

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compounds on avian embryos having less than 10,000 cells. One of ordinary skill in the art at the time of the invention would have been motivated to use the eggs of Tanaka, Johnston or Perry in teratogenic studies to determine if manipulating eggs as taught by Tanaka, Johnston or Perry effect teratogenesis.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

Claims 59-80 of this application conflict with claims of Application No. 09/784803. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg.*

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Co., 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 59-80 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims of copending Application No. 09/7845803. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL C. WILSON
PATENT EXAMINER